IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

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In re:

AREDIA and ZOMETA
PRODUCTS LIABILITY LITIGATION
(MDL No. 1760)

No. 3:06-MD-1760
JUDGE CAMPBELL
MAGISTRATE JUDGE BROWN

This Document Relates to: **All Cases**

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PROPOSED CASE MANAGEMENT ORDER

This Case Management Order is hereby entered in all actions in *In re: Aredia® and Zometa® Products Liability Litigation*, No. 3:06-MD-1760 (M.D. Tenn.) ("MDL 1760").

This Order shall apply to all cases currently a part of MDL 1760, as well as all cases subsequently filed in, removed to, or transferred to this Court as part of MDL 1760. In cases subsequently filed in this District, the Clerk shall provide a copy of this Order to each plaintiff at the time of filing of the complaint. In cases subsequently removed or transferred to this Court, the Clerk shall provide a copy of this Order to each new party upon removal or transfer. This Order vacates any prior case management or scheduling order issued by a federal court prior to the transfer of a case to MDL 1760, including the case management orders entered in matters pending before this Court prior to entry of the Order of the Judicial Panel on Multidistrict Litigation ("JPML") creating this MDL. The local rules of a federal transferor court will not be binding on the parties once a case has been transferred to this MDL so long as the case remains before this transferee court. As it relates to any event or filing in MDL 1760, the term "party" means plaintiffs collectively and Novartis Pharmaceuticals Corporation individually. This Order shall be binding on all parties with cases docketed in MDL 1760.

I. JURISDICTION AND VENUE.

A. The Plaintiffs contend that jurisdiction exists under 28 U.S.C. § 1332 because there is diversity of citizenship and the amount in controversy exceeds $75,000 exclusive of interests and costs. Plaintiffs contend that venue is proper pursuant to 28 U.S.C. § 1391(a)(1) because the Defendant is subject to personal jurisdiction here and is therefore deemed to reside in this district for venue purposes pursuant to 28 U.S.C. § 1391(c).

B. For the purposes of pre-trial proceedings, defendant has not challenged the existence of diversity jurisdiction, but reserves the right to challenge venue as appropriate under 28 U.S.C. § 1404 or other applicable statutes.

II. STATUS OF SERVICE AND RESPONSIVE PLEADINGS.

A. Plaintiffs have effectuated service on the single defendant of the cases currently in MDL 1760 as of the date of this Order. There is no dispute regarding service in those cases. However, defendant is not precluded from challenging the sufficiency of service in any case not currently part of MDL 1760.

B. All proceedings in any case transferred to MDL 1760, now or in the future, are stayed except (i) specific proceedings outlined in this Order or any subsequent order of the Court, or (ii) any pending motions to remand presently before this Court. All prior written discovery requests to which responses have not yet been served are deemed withdrawn and the party upon whom the written discovery was served has no obligation to respond. All deadlines for filing an answer or pre-answer motion are hereby stayed until sixty (60) days after the Clerk of this Court establishes a specific case number for the case in the United States District Court for the Middle District of Tennessee or the original complaint is served, whichever is later.

III. PARTIES' THEORIES OF THE CASE.

A. **Plaintiffs' Theory of the Case.** Since, 1991, 1.9 million people have been treated with Aredia. Since 2001, one million people have been treated with Zometa. According to Novartis, Zometa is today the most widely used bisphosphonate in oncology. The Plaintiffs seek compensatory damages and punitive damages for personal injuries. The theories of liability are strict liability and negligence. In addition, the Plaintiffs seek certification of a class action for the creation of a dental monitoring program for persons exposed to the drugs who do not yet have osteonecrosis of the jaw. The large number of persons treated with Aredia and Zometa establish that, when certified, the class will be made up of thousands of people who have taken both drugs.

Novartis filed a New Drug Application (NDA) for Aredia on December 20, 1989. The NDA was approved by the Food and Drug Administration (FDA) on October 31, 1991. At that time, the approved use was for the treatment of hypercalcemia of malignancy (HCM). Subsequently, Aredia was approved for the treatment of Paget's disease, osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma.

On December 21, 1999, Novartis filed a NDA for Zometa. The NDA was approved by the FDA on August 20, 2001. As of that date, the approved use was for HCM. Subsequently, Zometa was approved for the treatment of multiple myeloma and documented bone metastases from solid tumors.

Both Aredia and Zometa are bisphosphonates. Bisphosphonates contain phosphorus. In 2001, the FDA began receiving reports of osteonecrosis of the jaw (ONJ) associated with bisphosphonate therapy. This should have come as no surprise to Novartis. "Phossy jaw" first appeared in a case series reported in Vienna in 1845. The condition was caused by exposure to

white phosphorous during the manufacture of matches. The average time from first exposure to diagnosis was five years. Occasionally, the period was as short as a few months. Also, it has been reported that once taken, bisphosphonates remain in the body for more than twelve (12) years.

Novartis admits receiving reports of ONJ in cancer patients treated with bisphosphonates as early as December, 2002. As of that date, the labeling for Aredia and Zometa contained no warnings or other information about ONJ. This is so even though the clinical trials for both Aredia and Zometa contained patients with findings consistent with ONJ.

Novartis finally took some action in September, 2003, when the package insert for Zometa was revised to contain the following language under post-marketing experiences in the adverse events section:

> Cases of osteonecrosis (primarily of the jaws) have been reported since market introduction. Osteonecrosis of the jaws has other well documented multiple risk factors. It is not possible to determine if these events are related to Zometa or other bisphosphonates, to concomitant drugs or other therapies (e.g., chemotherapy, radiotherapy. corticosteroid), to patient's underlying disease, or to other comorbid risk factors (e.g., anemia, infection, preexisting oral disease).

There were no changes made at that time to the package insert for Aredia.

In October, 2003, Novartis finally took some action with regard to Aredia when the following paragraph was added to the package insert under post-marketing experiences in the adverse events section:

> Cases of osteonecrosis (primarily of the jaws) have been reported since market introduction. Osteonecrosis of the jaws has other well documented multiple risk factors. It is not possible to determine if these events are related to Zometa or other bisphosphonates, to concomitant drugs or other therapies (e.g., chemotherapy, radiotherapy, corticosteroid), to patients's underlying disease, or to other comorbid risk factors (e.g. anemia, infection, preexisting oral disease).

In 2003, Robert E. Marx, DDS, Chairman of Oral and Maxillofacial Surgery at the University of Miami School of Medicine, published a letter to the editor of the *Journal of Oral and Maxillofacial Surgery* wherein he described 36 cases of painful bone exposure in the mandible, maxilla or both, that were unresponsive to surgical or medical treatment. These patients had received either Aredia, Zometa, or both.

In November, 2003, the FDA Office of Drug Safety (ODS) began a search of the FDA's Adverse Event Reporting System for reports of cases of osteonecrosis or osteomyelitis associated with the use of Aredia, Zometa, Fosamax, or Actenol. In a memorandum dated August 25, 2004, the ODS identified 139 cases of which 47 had taken Aredia only, 33 had taken Zometa only, and 59 had taken both Aredia and Zometa. The review concluded that the language in both the Aredia and Zometa package inserts needed to be changed to highlight this adverse event as being associated with the therapeutic class of bisphosphonates. In addition, the review concluded that the labeling should be changed to reflect that the condition could be osetonecrosis, osteomyelitis or a combination of the two.

In 2004, Salvatore L. Ruggiero, DMD, MD, Chief of Oral and Maxillofacial Surgery at the Long Island Jewish Medical Center, in collaboration with others, published an article in the *Journal of Oral and Maxillofacial Surgery* in which he described 63 cases of necrotic lesions in the jaw. All 63 had one thing in common: they had all received chronic bisphosphonate therapy. Of the 63 patients, 57 had taken either Aredia or Zometa, or both.

On March 4, 2005, the Oncologic Drugs Advisory Committee of the FDA conducted a public hearing during which testimony was presented relating to the connection between bisphosphonate therapy and osteonecrosis of the jaw. Part of the testimony included an analysis

of the mean time from exposure to the appearance of suspicious findings. For Aredia, the mean time was just under six years; for Zometa, 18 months. The need for monitoring was acknowledged by Novartis and it submitted to the Committee a list of recommendations for the prevention, diagnosis and treatment of osteonecrosis of the jaw. These recommendations are a starting point for the creation of the dental monitoring program sought by Plaintiffs in their complaint and request for class certification. Novartis's recommendations include: education of patients regarding the importance of good dental hygiene and symptom reporting; physical and dental evaluation; and imaging with panoramic radiographs. Novartis further recommended that these evaluations occur at a minimum of every six months.

The facts clearly establish that Novartis knew or should have known of the risk of osteonecrosis and/or osteomyelitis of the jaw at the time it first sold Aredia in 1991 and Zometa in 2001. That knowledge only increased with time, yet Novartis did nothing to warn prescribers or users of Aredia until October, 2003 and of Zometa until September, 2003. Even then, the warnings provided were inadequate and were not made available to dentists or oral surgeons. This inexcusable failure to warn supports Plaintiffs' claim for punitive damages and the necessity for a dental monitoring program. The facts establish the existence of a readily definable class of thousands of persons who took both Aredia and Zometa and which have already developed, or are at significant risk of developing, osteonecrosis and/or osteomyelitis of the jaw. The funding by Novartis of a dental monitoring program similar to, but more complete than the one recommended to the FDA earlier this year, will serve to reduce the risk of developing these conditions. It will also lead to a more timely diagnosis and treatment of the conditions should they develop.

B. **Defendant's Theory of the Case.**

Plaintiffs allegedly either have osteonecrosis of the jaw ("ONJ") or are at a significantly increased risk of developing it as a result of using Aredia® and/or Zometa®, both of which are distributed by Novartis Pharmaceuticals Corporation ("NPC").[1] Aredia® and Zometa® are used by cancer patients with multiple myeloma, metastases to the bone from certain types of cancers, or hypercalcemia of malignancy. Patients with multiple myeloma or bone metastases from solid cancerous tumors are susceptible to debilitating bone fractures, severe bone pain, spinal compression, and other skeletal related events ("SREs"). Hypercalcemia is increased calcium in the blood resulting from an imbalance in the bone remodeling process that occurs in some cancer patients. It can result in impairment of various bodily systems, coma, and death. Aredia® and Zometa® reduce the number, and delay the time to first onset, of SREs suffered by these patients and treat hypercalcemia of malignancy. As a result, these drugs provide significant, scientifically documented benefits to their users by enabling them to enjoy a vastly improved quality of life and avoid potentially grave complications of SREs and hypercalcemia.

ONJ is a rare, ill defined, and poorly understood condition with an undetermined etiology. There are multiple risk factors for developing ONJ, including but not limited to trauma to the jaw, dental surgery, cancer itself, treatment with corticosteroids, hormone therapy, and

[1] Aredia® is the trade name under which NPC distributes the drug pamidronate disodium for intravenous infusion. The Food and Drug Administration ("FDA") first approved it for use in 1991, and Aredia® is indicated for the treatment of hypercalcemia associated with malignancy; Paget's disease of bone; osteolytic bone metastases of breast cancer; and osteolytic lesions of multiple myeloma. Zometa® is the trade name under which NPC distributes the drug zoledronic acid for intravenous infusion. The FDA first approved Zometa® for use in 2001. Zometa® is indicated for the treatment of hypercalcemia of malignancy; multiple myeloma; and bone metastases from solid tumors (including prostate and other cancers).

poor dental hygiene. Further, there are several other disorders that present with symptoms similar to ONJ, but are in fact distinct conditions.

Plaintiffs' claims fail for several reasons. First, the claims are preempted. Plaintiffs' state law tort claims alleging that NPC's warnings were deficient conflict with the FDA's regulatory system – the same system that has continuously approved the labeling and marketing for Aredia® and Zometa® – and therefore must be dismissed.

Second, no scientifically reliable evidence establishes a causal relationship between treatment with Aredia® or Zometa® and ONJ. Plaintiffs only refer to unreliable case reports or retrospective chart reviews – none of which are a suitable basis for a causation determination under applicable law. Additionally, no dependable science establishes a mechanism of action regarding how either product allegedly causes ONJ.

Third, under any applicable legal standard, including but not limited to: a risk/benefit analysis; the Restatement (Second) of Torts § 402A, Comment K; or Restatement (Third) of Torts Product Liability §§ 4, 6, any alleged undisclosed risk posed by treatment with either or both drugs is outweighed by the benefits provided by them, thereby defeating plaintiffs' claims. Aredia® and Zometa® allow seriously ill cancer patients to engage in more of their normal activities because of the substantially reduced risk of SREs. Even if reliable science were to establish that ONJ is a possible side effect of using either product (which it currently does not), expert and other testimony will demonstrate that physicians prescribed and will continue to prescribe Aredia® and Zometa® because their benefits clearly outweigh any alleged risks and physicians would likely prescribe the drugs regardless of what language is or was in place in the labeling.

Fourth, plaintiffs have identified no safer alternative design and have provided no evidence that the state of the art, assumption of risk, the learned intermediary doctrine, or other similar defenses are inapplicable. The labeling has always contained various warnings approved by the FDA as appropriate at the given time.

In addition to the above substantive deficiencies, plaintiffs' request for a dental monitoring class fails to satisfy Federal Rule of Civil Procedure 23's certification requirements. In this MDL, the "general causation" inquiry will focus in part on whether either Aredia® or Zometa® can be isolated as the cause of ONJ in cancer patients receiving chemotherapy, radiation treatments, or other treatments or with other conditions that are independent risk factors for ONJ. Similarly, the specific causation analysis is inherently individual – it will require an examination of, among other things, each individual's medical history, what other risk factors for ONJ are present in that plaintiff, and what treatment protocol is appropriate for that plaintiff given his or her inherently unique circumstances. Further, plaintiffs suffer from several different cancers and were prescribed the drug(s) by different doctors at different times, thereby potentially receiving different information regarding the risk associated with Aredia® or Zometa® use. In addition to sharing no meaningful common factual issues, plaintiffs seek a nationwide medical monitoring class even though no uniformity exists among various states' laws on either the availability of medical monitoring as either an independent cause of action or a remedy or on the elements of the underlying medical monitoring cause of action. Class certification is inappropriate in such circumstances.[2]

[2] For many of the same reasons, the individual plaintiffs' claims are not properly joined in one action, even under the permissive standards of Federal Rule of Civil Procedure 20(a). *See Thorn, et al. v. Novartis Pharms. Corp.*, No. 3:04-CV-586 (E.D. Tenn. Aug. 30, 2005) (Docket #s 73, 74) (Jordan, S.J.) (denying joinder in part because

Medical monitoring is not an appropriate remedy in these cases because plaintiffs cannot meet any potentially applicable state law burden for such relief, including for example showing that a substantially increased risk exists, that uniformly useful diagnostic testing is available to allow "early detection", or that uniform preventative measures apply.

IV. MOTIONS AND SERVICE.

A. Motions. Motion practice shall be governed by applicable Federal and Local Rules except as otherwise provided herein or in any subsequent case management order. Absent an Order of the Court, briefs in response to all motions shall be filed no later than twenty-eight (28) days after the date of service. Replies may be filed without leave of Court, and shall be filed within fourteen (14) days after service of the response. In calculating the time periods set forth in this Order, the provisions of Fed. R. Civ. P. 5 and 6 apply. No additional memorandum of law shall be permitted without leave of court.

B. Service of Documents Not Filed With the Court. A party serving a document not filed with the Court that applies to all cases in the MDL shall provide one (1) copy to Plaintiffs' Liaison Counsel and one (1) copy to Defendant's Lead Counsel. Plaintiff's Liaison Counsel will be responsible for providing copies of the document to all other plaintiffs' counsel. A party serving a document not filed with the Court that applies only to a specific action or actions shall provide one (1) copy to Designated Counsel as described below in the specific action or actions and one (1) copy to Defendant's Lead Counsel. Service shall be made via U.S. Mail and either electronic mail in PDF format, overnight courier service, or facsimile

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proposed plaintiffs' claims did not arise out of the same transaction or occurrence as pending claims). The personal injury claims are also ill suited for certification under Rule 23.

transmission, reserving to any counsel of record the right to waive, in writing, all or any aspect of said service.

V. SUBSTITUTION OF PLAINTIFFS.

In the event that a plaintiff dies before his or her individual action is remanded, the following procedures shall govern the substitution of an individual as plaintiff in place of the deceased plaintiff:

A. Suggestion of Death. Within thirty (30) days of entry of this Order or the death of a plaintiff, whichever is later, plaintiff's counsel shall file a "Suggestion of Death" that identifies the plaintiff and describes the time, date, and circumstances of the plaintiff's death.

B. Timing of Motion for Substitution. The ninety (90) day time period for filing a Motion for Substitution, as required by Fed. R. Civ. P. 25(a), will commence upon the filing of a Suggestion of Death or upon the passage of 30 days from the entry of this Order, whichever is later.

C. Contents of Motion for Substitution.

1. The Motion for Substitution shall identify the proposed substitute plaintiff by name and shall describe why the proposed substitute plaintiff is a "proper" party and why the claim has not been extinguished under the applicable state survivorship statute or applicable state common law.

2. In the event that applicable state law requires the opening of an estate and the appointment of a personal representative to pursue the claims of a deceased plaintiff, plaintiff's counsel shall initiate or cause to be initiated proceedings to open an estate and/or obtain the

appointment of a personal representative for plaintiff within thirty (30) days of the plaintiff's death or thirty (30) days from entry of this Order, whichever is later.

a. If available at the time of filing, plaintiff's counsel shall attach a copy of any Order appointing the person sought to be substituted as the personal representative of the deceased plaintiff as an exhibit to the Motion to Substitute.

b. In the event that no personal representative has been appointed by the deadline for filing a Motion for Substitution, plaintiff's counsel shall describe in the Motion to Substitute the steps taken to obtain the appointment of a personal representative and state whether there are any competing applications. Plaintiff's counsel also shall attach to the Motion to Substitute all papers, pleadings, and petitions submitted in furtherance of that effort. If the Court determines that the person sought to be substituted would be a proper party if appointed a personal representative of the deceased plaintiff and that the provisions of this Section of the Order and Fed. R. Civ. P. 25(a) have otherwise been complied with, the Court will provisionally grant the Motion for Substitution on the condition that the substituted plaintiff submit to the Court prior to remand of the plaintiff's claims a copy of the Order appointing him or her as the deceased plaintiff's personal representative.

3. Plaintiff's failure to comply with the provisions of this Section, including the requirement that an Order appointing the substitute plaintiff as the decedent's personal representative be filed prior to remand where the Court grants a provisional substitution, will entitle defendant to a dismissal of plaintiff's action with prejudice in accord with Fed. R. Civ. P. 25(a).

D. Opposition to Substitution. Nothing in this section shall preclude defendant from challenging the authority or capacity of the proposed substitute plaintiff.

E. Rights of Substitute Plaintiff. By granting the motion for substitution, the Court is not bestowing on the substitute plaintiff any rights or remedies not otherwise available under applicable state law.

VI. PRE-TRIAL PROCEEDINGS.

A. Rule 26(a)(1) Disclosures. Defendant's Fed. R. Civ. P. 26(a)(1) disclosures made in *Anderson, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0718 (M.D. Tenn.), *Becker, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0719 (M.D. Tenn.), and *Wood, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0716 (M.D. Tenn.) shall constitute defendant's initial disclosures in all cases transferred into MDL 1760. Defendant shall supplement these disclosures as appropriate. Submission of a Plaintiff's Fact Sheet ("PFS") as described elsewhere in this Order that is complete in all respects shall satisfy that plaintiff's initial disclosure obligations under Fed. R. Civ. P. 26(a)(1).

B. Meeting of Counsel and Parties to Discuss Settlement Prospects. At this stage of the proceedings, the parties are in agreement that settlement is unlikely and also believe that ADR would not be productive.

C. Status of the Issues Presented. The issues and facts in this case are in dispute at this time.

D. Other Claims. At this time the parties are not aware of the need for any counterclaims, cross-claims, third-party claims, joinder of the other parties or claims. Should the parties become aware of the need for such pleadings, they will inform the other.

E. Authentication. It is hereby ordered that copies of all documents maintained in "hard" form produced by defendant are deemed to be a true and accurate copy of documents in the possession and control of that defendant, unless otherwise indicated on the face of the copy produced or disclaimed. It is further ordered that the "hard" copies of all documents maintained in electronic form produced by defendant are deemed to be a true and accurate representations of the data or other information maintained in electronic format by that defendant, unless otherwise indicated on the face of the "hard" copy produced or disclaimed. It is further ordered that all documents produced by plaintiffs, any physician, psychiatrist, hospital, clinic, or any other health care provider that treated any plaintiff and any documents obtained from insurance companies, employers, or state or federal governments are deemed a true and accurate copy of hard copy documents, including x-rays or films, if any, and "hard" copy documents or electronic documents produced by such persons or entities are deemed a true and accurate representation of the data or other information maintained in electronic format, unless otherwise indicated or disclaimed. The parties may request admissions of fact and/or stipulations regarding the authenticity of documents pursuant to Fed. R. Civ. P. 36.

F. Appearance of Counsel.

1. **Plaintiffs' Liaison Counsel/Committee Structure.** The Court designates Charles Patrick Flynn to serve as Plaintiffs' Liaison Counsel. A separate order designating the duties of Liaison Counsel, providing the initial structure of committees of Plaintiffs' counsel and their duties shall also be tendered. Any party objecting to any portion thereof may object within ten days after its filing.

2. **Defendant's Lead Counsel in MDL 1760.** Joe Hollingsworth and Katharine Latimer, of the law firm of Spriggs & Hollingsworth, 1350 I Street, N.W., Washington, D.C., 20005, are hereby designated Lead Counsel for defendant.

3. **Designated Counsel.** In each specific action, plaintiffs will each designate one attorney to act as Designated Counsel for purposes of receiving service. Each plaintiff will file a Notice of Designation in each specific action naming their Designated Counsel within fifteen (15) days of the entry of this Order or the docketing of the action in MDL 1760, whichever is later.

G. Counsel Communications. In addition to the local rule requirement of counsel communication before submission of discovery disputes to the Court, counsel shall attempt to confer in good faith to resolve all issues before submission of any matter to the Court. Further, discovery disputes shall be informally brought to the attention of the Magistrate Judge by a telephone conference on which all parties are represented before submission of any discovery dispute to the Court by motion.

VII. WRITTEN DISCOVERY – GENERALLY.

A. Compliance with Rules. Except as expressly set forth herein, and absent an agreement of the parties under Fed. R. Civ. P. 29 or an order of the Court to the contrary, all discovery shall be conducted with and comply with the provisions of the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the Middle District of Tennessee.

B. Confidentiality of Produced Materials or Deposition Testimony. The parties will submit to the Court for approval a jointly-agreed upon Protective Order that will govern all actions and counsel involved in this MDL.

Any inadvertent or unintentional production of any confidential or proprietary material will not be construed as a waiver, in whole or in part, of (a) the producing party's claims of confidentiality either as to the specific information inadvertently or unintentionally disclosed or more generally as to the subject matter of the information disclosed, or (b) the party's right to designate the material as confidential pursuant to the Protective Order. In the event that a party inadvertently or unintentionally produces any confidential material without attaching one of the legends described in the Protective Order, the party may subsequently designate the material as Confidential at any time by forwarding to the opposing party copies of the material bearing one of the legends required by the Protective Order and requesting that the opposing party destroy all prior copies of the Confidential Material. Upon receipt of such a request, the opposing party shall destroy all copies of the Confidential Material produced inadvertently and replace them with copies bearing the appropriate confidentiality legend.

C. Assertion of Privilege in Response to Production Requests. Any party that withholds the production of requested documents or materials, regardless of the manner in which they are kept or maintained, on the ground of any privilege or application of the work-product doctrine must specify in writing, as to each document or thing not produced, the specific privilege(s) or doctrine(s) it is relying upon to withhold each document ("Privilege Log"). Each Privilege Log shall describe each document or thing to which a privilege or work product doctrine is asserted in sufficient detail to reasonably permit the party seeking discovery to assess

whether or not to dispute any such assertion of privilege or application of the work product doctrine, unless such detail would destroy the privilege. A Privilege Log need not be produced contemporaneously with the documents, but may be produced at reasonable rolling intervals subsequent to production. Documents that were created or generated subsequent to the filing of the constituent actions to this proceeding, or the filing of other actions asserting allegations similar to those asserted in the constituent actions, and which concern or relate directly to the defense of a specific lawsuit or lawsuits and are privileged as communications or work product relating to the defense of those actions need not be placed on a Privilege Log.

The inadvertent production by any party in the course of discovery in these proceedings of a document subject to a claim of privilege, work product, or other statutory or court-ordered confidentiality, will not result in a waiver of any of the foregoing protections, whether in these or any other proceedings, for the produced document or any other withheld document covering the same or similar subject matter. If any party should inadvertently produce a document, upon notice of such disclosure, all originals and copies thereof, as well as all notes or other work product reflecting the contents of such materials, shall be immediately returned to the producing party, and such returned material shall be deleted from any litigation-support or other database.

D. Preservation of Documents.

1. While this Order remains in effect, each of the parties herein who receive actual notice of this order by personal service or otherwise, are restrained and enjoined from altering, destroying, permitting the destruction of, or in any other fashion changing any document or tangible item in the actual or constructive care, custody, or control of such person that is reasonably within the scope of discovery in this case, wherever such document or tangible item is

physically located. Except as otherwise provided below, this Order imposes no duty on any party to notify any agents or third parties regarding this Order and parties have no responsibility for actions taken by agents or third parties unless taken at the direction of a party.

2. Defendant's obligation to preserve documents (including but not limited to electronic data and e-mail) created subsequent to the effective date of this Order ("newly created documents") is limited to only those company employees who, during the regular course of their employment, would be responsible for or directly oversee others responsible for any of the following subjects and is limited to documents relating to any of the following subjects:

a. The regulatory status of Aredia® and Zometa®;

b. The risk or occurrence of osteonecrosis of the jaw in patients treated with Aredia® or Zometa®;

c. The collection and/or reporting of adverse reactions occurring in patients treated with Aredia® or Zometa®; and

d. The number and identity of individuals asserting claims against defendant for injuries sustained while using Aredia® or Zometa®.

3. Each plaintiff must forward a copy of the letter attached to this Order as Exhibit A to each of his or her treating physicians and any hospital or clinic that treated plaintiff, thereby notifying those persons of the terms of this Order.

4. The duty to preserve newly created documents shall not extend to (a) documents that are protected by the attorney client privilege or work product doctrine, including, but not limited to, briefs, motions, legal or factual memoranda, notes, communications or other similar materials created in anticipation of or during the course of any litigation concerning

Aredia® or Zometa® by or for any attorney representing any party to the proceedings coordinated in this Court, or in any other legal proceedings involving Aredia® or Zometa®; (b) documents consisting of temporary compilation of information, such as dictation, drafts, and interim versions of documents, if such temporary compilations of information would not have been preserved in the ordinary course of business; and (c) multiple identical copies of a document, including photocopies and electronically-stored data so long as the original document, or an identical copy thereof, remain in the possession, custody or control of a party. The retention of full back-up of any server or other computer on a monthly basis shall relieve the party of any obligation to maintain any incremental or interim back-ups of such server or other computer. Nothing in this Order shall require any party to implement any procedure relating to the backing-up of electronic data that such party does not already have in place.

5. The preservation obligations of this Order are not intended to displace, lessen, or heighten any parties' preservation obligations pursuant to law.

VIII. FACT DEPOSITIONS — GENERALLY.

A. Deposition Procedure. Unless otherwise agreed by all parties before a deposition, depositions will proceed according to the Federal Rules of Civil Procedure and Local Rules, except as specified below. Any agreement to deviate from the Federal Rules of Civil Procedure, the Local Rules of this Court, or this Order must be recorded on the transcript at the time the deposition commences.

B. Scheduling.

1. Plaintiffs may commence depositions of defendant's current and former employees no earlier than sixty (60) days from the date of this Order. Unless otherwise agreed

by the parties, all notices of deposition seeking to depose defendant's current or former employees, including all notices propounded pursuant to Fed. R. Civ. P. 30(b)(6), must be served at least 45 days prior to the noticed deposition date.

2. To allow for the collection of medical and other records, except as otherwise provided herein, otherwise agreed to by the parties, or otherwise ordered by this Court, other case-specific fact depositions noticed by either party, including but not limited to depositions of plaintiffs, treating and consulting physicians, and family and friends of plaintiffs, may commence no earlier than one hundred and fifty (150) days after the plaintiff serves a PFS complete in all respects, as described below.

3. If there is a material risk that the plaintiff may become incapacitated – that is to become physically or mentally incapable of providing complete and accurate testimony – or perish at any time prior to the expiration of the 150 day period discussed above, plaintiff's counsel may take a preservation deposition of the plaintiff after:

a. Providing reasonable notice to defendant of the intention to take such a deposition;

b. Providing an affidavit or declaration from plaintiff's physician setting forth the circumstances of the plaintiff's health and the reason that such a deposition is necessary; and

c. Submitting to defendant at least fourteen (14) days before the deposition is scheduled a PFS that is complete in all respects.

Defendant is entitled to take a discovery deposition of the plaintiff before the taking of a preservation deposition. Should there be outstanding requests by defendant for medical records

at the time that a preservation deposition taken under this paragraph is commenced, that fact will be noted on the record by defendant's counsel. In the event that the plaintiff is not incapacitated at the time that defendant has obtained all requested medical records related to plaintiff, defendant shall be entitled to take a second deposition of plaintiff or to take an initial deposition of plaintiff if defendant declined the opportunity to take a discovery deposition prior to plaintiff's counsel taking a preservation deposition. Any time used by plaintiffs in conducting a deposition pursuant to the terms of this section shall not reduce the defendant's permitted time to conduct that deposition as set forth in elsewhere in this Order. In all other respects, depositions conducted by plaintiffs pursuant to this order shall comply with the applicable deposition procedures and protocols established in this Order.

4. Counsel shall attempt in good faith to cooperate in the scheduling of depositions permitted in this section considering the demands on the time and schedules of both the parties and their respective counsel. Counsel shall meet and confer as soon as practicable to resolve any scheduling dispute(s).

C. Length of Direct Examination in Fact Depositions. Except as otherwise stated in this paragraph, the examination by the party noticing the deposition shall be no more than seven (7) hours of actual examination time absent agreement or further order of this Court upon a showing of good cause. The Court expects that if a deposition requires additional time, the parties will make a good faith effort to agree on an extension before coming to the Court for resolution. A deposition of a treating physician may be taken more than once if that physician has treated more than one plaintiff. In such circumstances, the noticing party will be entitled to seven (7) hours of deposition questioning of the witness for each plaintiff the witness treated.

D. Production of Documents by Deposition Witnesses. Witnesses subpoenaed or noticed to testify and to produce documents shall be noticed and served with the subpoena or deposition notice and document request at least forty-five (45) days before the scheduled deposition. Depending upon the quantity of documents to be produced by deponent, some time may be needed for inspection of the documents before the interrogation commences. Time spent examining documents produced by the deponent at a deposition is not considered examination time. Responsive documents that are identical to those already produced in discovery to the plaintiffs or to the defendant do not have to be produced by the deponent.

E. Location of Depositions. Unless otherwise agreed by the parties, depositions shall be taken in the federal district where the deponent resides or maintains his or her place of business.

F. Conduct of Depositions.

1. **Cooperation**. Counsel are expected to cooperate with, and be courteous to, each other and deponents during the course of any deposition. Counsel shall recess from time to time during the deposition for meals and to permit periods of rest or refreshment reasonably required by the deponent, stenographer(s) and/or counsel conducting or defending the deposition.

2. **Deposition Day**. Absent agreement of the parties to the deposition, a deposition day shall be no longer than seven (7) hours of actual examination time.

3. **Continuance of Deposition**. Depositions will not be noticed from day to day, but will be noticed for a single, specific day. Should a deposition not be completed on the scheduled day, the deposition will continue on a date agreed upon by the parties. If there is no agreement on when the deposition will be continued, a notice of continued deposition may be

served providing at least ten (10) days notice of the date upon which the deposition will be continued.

4. **Examination**. The party noticing a fact deposition shall designate one attorney to conduct the examination of the deponent.

5. **Disputes During Depositions**. Disputes between the parties arising during a deposition should be addressed to this Court rather than to the district court in which the deposition is being conducted.

6. **Copies of Exhibits**. A copy of any document about which examining counsel expects to question the deponent should ordinarily be provided to primary counsel for the parties and for the deponent at the time presented to the deponent and his/her counsel.

G. Stenographic Recording. A certified court reporter shall stenographically record all deposition proceedings and testimony. The court reporter shall administer the oath or affirmation to the deponent. A written transcript by the court reporter, together with copies of all exhibits marked or referred to during the deposition, shall constitute the official record of the deposition for purposes of Fed. R. Civ. P. 30(e) (submission to the witness) and Fed. R. Civ. P. 30(f) (filing, exhibits). The transcript shall also contain the name of any attorney and any other person attending the deposition together with the name of his or her firm or organization, business address and, if applicable, the name of the person or organization he or she represents.

H. Videotaped Depositions. Any deposition may be videotaped at the request of any party, provided that the deposition notice or subpoena contains or is accompanied by a notice that the deposition will be videotaped, under the following terms and conditions:

1. All videotaped depositions shall be simultaneously stenographically recorded in accordance with this Order.

2. The party requesting videotaping of the deposition shall bear the expense of both the videotaping and the stenographic recording. Requests for the taxation of these costs and expenses may be made at the conclusion of the litigation in accordance with applicable law.

3. The operator(s) of the videotape recording equipment shall be subject to the provisions of Fed. R. Civ. P. 28(c). At the commencement of the deposition, the operator(s) shall swear or affirm to record the proceedings fairly and accurately.

4. At the commencement of the deposition, each witness, attorney and any other person attending the deposition shall identify themselves on camera.

5. No attorney or party shall direct instructions to the video operator(s) as to the method of operating the equipment. The video camera operation will be suspended during the deposition only upon stipulation by counsel for "off the record" discussions and for the videographer to change the tape if needed. The video operator(s) shall record on camera the time of suspension and any subsequent reconvening of the deposition.

6. The deposition will be conducted in a manner to replicate, to the extent feasible, the presentation of evidence at trial. Unless physically incapacitated, the deponent shall be seated at a table except when reviewing or presenting demonstrative materials for which a change in position is needed. To the extent practicable, the deposition will be conducted in a neutral setting, against a solid background, with only such lighting as is required for accurate video recording. Lighting, camera angle, lens setting, and field of view will be changed only as necessary to record accurately the natural body movements of the deponent or to portray exhibits

and materials used during the deposition. Sound levels will be altered only as necessary to record satisfactorily the voices of counsel and the deponent.

7. If the party noticing the deposition does not intend to convert the videotape to digital form, the videographer shall use a counter on the recording equipment and after completion of the deposition shall prepare a log, cross-referenced to counter numbers, that identifies the depositions on the tape at which examination by different counsel begins and ends, at which objections are made and examination resumes, at which exhibits are identified, and at which any interruption of continuous tape-recording occurs, whether for recesses, "off-the-record" discussions, mechanical failure, tape changes, or otherwise.

8. After the deposition is completed, the video operator(s) shall certify on camera the correctness, completeness, and accuracy of the videotape recording in the same manner as a stenographic court reporter, and file a true copy of the video tape, the transcript, and certificate with counsel for whomever noticed the deposition.

9. Technical data, such as recording speeds and other information needed to replay or copy the tape, shall be included on copies of the videotaped deposition.

I. Copies of Transcripts and Videotapes. Subject to any restrictions contained within the protective order entered in this litigation, any party may at its own expense obtain a copy of the videotape and the stenographic transcript by contacting counsel that noticed the deposition or the court reporter.

J. Correction and Signing of Depositions. Unless waived by the deponent, the transcript of a deposition, or any portion thereof, shall be submitted to the deponent for reading, correction, and signature within thirty (30) days after the completion of the deposition or any

portion thereof. A deposition transcript, or a transcript of a portion thereof, may be signed by the deponent before any notary within thirty (30) days after the transcript, or any portion thereof, is submitted to the deponent. If no corrections are made during this time, the transcript will be presumed accurate.

IX. DISCOVERY FROM DEFENDANT.

A. Production of Documents.

1. **Prior Production and Responses to Requests to Produce**. Requests for production have been propounded on and answered by defendant in several cases. Within fifteen (15) days of the entry of this Order, defendant will supplement its prior answers to requests for production in *Anderson, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0718 (M.D. Tenn.), *Becker, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0719 (M.D. Tenn.), and *Wood, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0716 (M.D. Tenn.) and provide the same to any plaintiff who requests copies. Defendant's answers to requests for production in these referenced cases shall be applicable to any case docketed in this MDL. All objections raised previously by defendant in response to requests for production are preserved, and all rights held by plaintiff(s) to contest any objections made are similarly preserved. In addition, defendant may assert additional objections, if any, in response to the previously served requests for production within fifteen (15) days of the entry of this Order.

2. **Additional Requests to Defendant For Production of Documents**. As described below, defendant is producing millions of pages of documents in response to the requests for production made in *Anderson, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0718 (M.D. Tenn.), *Becker, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0719

(M.D. Tenn.), and *Wood, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0716 (M.D. Tenn.). In the absence of an agreement of the parties, no further document requests may be propounded to defendant without leave of Court.

3. **Protocol of Document Production.**[3] The following protocol shall apply to the production of documents existing in hard-copy form and, as limited below, documents existing in native electronic form by defendant:

a. **General**. Except as limited below, all documents that originally existed in either hard-copy or native electronic form that are not privileged or otherwise protected from production and are responsive to discovery requests or Court order (or are otherwise produced in these proceedings) shall be produced in electronic image form in the manner provided herein. Each document's electronic image shall convey the same information and image as the original document. Documents that present imaging or formatting problems shall be promptly identified; the parties shall meet and confer to attempt to resolve the problems.

b. **Document Image Format**. All hard-copy documents shall be scanned as black and white images at 300 d.p.i. resolution and shall be saved and produced in a Group 4 compression single-page "TIFF" format. All native electronic documents shall be saved electronically (or "printed") in a Group 4 compression single-page "TIFF" image that reflects how the source document would have appeared if printed out to a printer attached to a computer viewing the file. Defendant shall produce a "load file" to accompany the images, which load file

[3] Defendant has provided this proposed document production protocol to plaintiffs' counsel. Plaintiffs' counsel agreed with the protocol pending clarification regarding the definition of a technical term. Defendant is in the process of obtaining that information and will provide it as soon as possible. Defendant is confident the parties will be able to reach agreement on this issue.

shall facilitate the use of the produced images by a document management or litigation support system. The parties shall meet and confer to the extent reasonably necessary to facilitate the import and use of the produced materials with commercially available document management or litigation support software.

c. **Document Unitization**. Each page of a document shall be scanned into an image and if a document is more than one page, the unitization of the document shall be maintained.

d. **"Bates Numbering."** Each page of a produced document shall have a legible, unique page identifier ("Bates Number") electronically "burned" onto the image at a location that does not obliterate, conceal, or interfere with any information from the source document except where such information has been redacted in accordance with applicable law or a Court order. Each document shall also have a "confidential" legend electronically "burned" onto the image at the bottom of each page in such a way so as not to obliterate, conceal or interfere with any information from the source document. In addition, each page shall bear a "MDL" watermark across the face of the document in a way so as not to obliterate, conceal, or interfere with any information from the source document. At the time of trial, defendant will provide "clean" copies of all documents that plaintiffs intend to use at trial as indicated by the exhibit list the parties shall exchange pursuant to the final pre-trial order or other Court order.

e. **File Naming Conventions**. Each document image file shall be named with the unique Bates Number of the page of the document in the case of single-page TIFFs, followed by the extension ".TIF".

f. **Production Media**. Defendant shall produce documents on CD-ROM, DVD, external hard drive (with standard PC compatible interface), or such other readily accessible computer or electronic media as the parties may hereafter agree upon (the "Production Media"). Each piece of Production Media shall identify its general contents, *e.g.*, "Zometa® New Drug Application," "Aredia® New Drug Application," "John F. Smith's Documents," etc., as well as the volume of the material in that production.

g. **Production of Hard-Copy Documents from Defendant's Employees and Archive Documents**. Hard-copy documents located by defendant during review of defendant's archives and business premises will be produced in the manner described in paragraph 2, above, for hard-copy documents. Defendant has elected to have these documents objectively coded. Accordingly, upon the production of documents within this category (or upon creation of the objective coding), defendant will produce an ASCII text file, appropriately delimited, setting forth the objective coding for each document (the "Objective Coding"). The Objective Coding shall contain the following information: Author, Recipient, Date, Subject Line/Title (if applicable), Document Type, and Copyees. If plaintiffs have problems importing and using the Objective Coding for document management, plaintiffs and defendant shall meet and confer to attempt to resolve the problems. Defendant's production of Objective Coding shall not constitute any certification as to the reliability, accuracy or completeness of the coding, and shall not constitute any waiver of work product protection or the attorney-client privilege with respect to that coding.

h. **Production of New Drug Application Files.** Documents encompassed within the New Drug Application ("NDA") files for Aredia® and Zometa® will be

produced in the manner described above, for hard-copy documents because that is the manner in which they are primarily maintained by defendant. The NDA documents have not been objectively coded. The NDAs contain a number of indices of particular sections. Defendant will produce the NDAs in the same order they were presented to the FDA, with all of the indices contained therein intact. Without waiving any work-product protection, defendant will provide a list of the Bates Number ranges that contain the volume indices it has located within the NDA files. Without waiving any work-product protection, defendant will also provide plaintiffs with a separate list that indicates the Bates Number range for and identifies the text appearing on the cover of each volume of the NDAs.

i. **Electronic Source Documents: Electronic Text Files.** Electronic documents maintained on network home directories and electronic mail, which exist natively in electronic format, will be produced in the manner described in paragraph 2, above, for native electronic documents. Defendant will also produce text files reflecting the full text that has been electronically extracted from the original, native electronic files ("Extracted Text"). The Extracted Text shall be provided in ASCII text format and shall be labeled and produced on Production Media. The text data will be provided in delimited ASCII format with the production bates number information. Defendant shall not be obligated to produce Extracted Text for documents that have been redacted in accordance with applicable law or Court order. For those documents, defendant will produce an ASCII file containing text obtained through the use of commercially-available optical character recognition ("OCR") software after redactions have been made. Should extracted text from an electronic source document contain privileged or

otherwise protected information, such production shall not be deemed a waiver of any privilege that might attach to the extracted text or the related document.

j. **Original Documents.** Defendant shall retain the original hard copy and native electronic source documents for all documents produced in this MDL proceeding. Subject to preservation of appropriate privileges and other protections of defendant's information from production in accordance with applicable law, defendant shall, upon reasonable request, make originals of any produced document available for inspection by the requesting party in the form in which such documents are kept in the ordinary course of business.

k. **Production of Other Electronic Documents.** This Protocol shall not apply to native electronic files (1) where access to the native electronic file or data contained within such file is material to the analysis, use, or understanding of the information or data within such file, or (2) that otherwise present imaging or pagination problems, including statistical analysis files and database files (such as mainframe-, DB2-, Access-, or Oracle-based files). Plaintiffs and defendant shall meet and confer to agree on the form for the production of these other electronic materials.

l. **Discovery and Admissibility**. Nothing in this Protocol shall be construed to affect the discoverability or admissibility of any document or data. All objections to the discoverability or admissibility of any document or data are preserved and may be asserted at any time.

B. Interrogatories to Defendant.

1. **Prior Answers to Interrogatories**. Interrogatories have been propounded to and answered by defendant in several cases. Within fifteen (15) days of the entry of this Order, defendant will provide answers to interrogatories in *Anderson, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0718 (M.D. Tenn.), *Becker, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0719 (M.D. Tenn.), and *Wood, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0716 (M.D. Tenn.) to any plaintiff who requests copies. Defendant's answers to interrogatories in these referenced cases shall be applicable to any case docketed in this MDL. All objections raised previously by defendant in response to interrogatories are preserved, and all rights held by plaintiff(s) to contest any objections made are similarly preserved. In addition, defendant may assert additional objections, if any, in response to the previously served interrogatories within fifteen (15) days of the entry of this Order.

2. **Additional Interrogatories**. In the absence of an agreement of the parties, no further interrogatories may be propounded to defendant without leave of Court.

C. Depositions of Defendant.

1. **Current Employees**. Plaintiffs shall in good faith take only those depositions of defendant and its current employees deemed reasonably necessary under the circumstances of this case. Defendant shall make available, without requiring a subpoena, all current employees requested by plaintiffs for deposition, subject to the limits set on the number of depositions set forth within this Order and to defendant's right to object to the taking of any particular employee's deposition for good cause shown.

2. **Former Employees**. Defendant shall take reasonable steps to make available requested former employees, to the extent possible. If defendant is unable, despite its

best good faith efforts, to produce former employees, then defendant shall provide upon request the former employee's last known address and shall cooperate in any effort to obtain this Court's, or another court's, assistance to compel the former employee's attendance at the deposition. Plaintiffs shall not contact former employees of defendant.

3. **Number of Depositions**. Plaintiffs shall be limited to ten (10) depositions of defendant's current employees and former employees, including depositions noticed pursuant to Fed. R. Civ. P. 30(b)(6). Absent agreement by the defendant, plaintiffs may apply to the Court to conduct further depositions or a subsequent deposition of an individual previously deposed only upon a showing of good cause and the specific identification of the individual(s) sought to be deposed.

X. DISCOVERY FROM PLAINTIFFS.

A. Plaintiff's Fact Sheet. Each plaintiff in each case filed in or transferred to the Court shall complete a separate PFS. Plaintiffs in all cases currently docketed in this Court as of the date of entry of this Order shall complete a PFS in all respects and serve the same upon Defendant's Lead Counsel in the applicable case as specified elsewhere this Order. Plaintiffs in all cases in which this Court receives the case file or cases filed in this Court but made part of MDL 1760 after the date of entry of this Order shall be served with a copy of the PFS by Plaintiffs' Liaison Counsel as described below and shall complete a PFS in all respects and serve the same upon Defendant's Lead Counsel and counsel of record in the applicable case.

B. Plaintiffs to Complete PFS in All Respects. Plaintiff(s) in each case filed in or transferred to the Court shall complete a PFS in all respects, including providing defendant with all applicable accompanying authorizations, within forty-five (45) days of service. To "complete

a PFS in all respects" means to answer every question on the PFS and leave no blanks, even if a plaintiff can only answer the question in good faith by indicating "not applicable" or "I don't know." This definition of "complete in all respects" shall be applicable throughout this Order.

C. Plaintiff's Failure to Serve PFS. Should any plaintiff fail to serve a PFS within the time allotted, Defendant's Lead Counsel shall send a warning letter to that plaintiff's Designated Counsel in the specific case involved, with a copy to the Plaintiffs' Liaison Counsel. Plaintiff shall have an additional fifteen (15) days to serve a PFS completed in all respects. The letter shall include a warning that the case is subject to dismissal under this Order if a PFS completed in all respects is not received within fifteen (15) days of the service of the warning. Should a plaintiff fail to provide a PFS completed in all respects (including signatures on all applicable authorizations) within fifteen (15) days of service of the warning letter, defendant is entitled to seek an Order to Show Cause why the case should not be dismissed. Any such filing shall be served on Plaintiff's Designated Counsel and Plaintiffs' Liaison Counsel, with any response to such filing to be submitted within ten (10) days following the date of service.

D. Plaintiff's Failure to Complete PFS in All Respects. If defendant receives a PFS in the allotted time, but the PFS is not completed in all respects, Defendant's Lead Counsel shall send a deficiency letter to that Plaintiff's Designated Counsel allowing plaintiff an additional fifteen (15) days to serve a PFS that is complete in all respects. The deficiency letter shall include a warning that the case is subject to dismissal under this Order if a PFS complete in all respects is not received within fifteen (15) days of service of the warning. Should a plaintiff fail to cure the deficiencies identified and fail to provide responses that are complete in all respects (including signatures on all applicable authorizations) within fifteen (15) days of service

of the deficiency letter, defendant is entitled to seek an Order to Show Cause why the case should not be dismissed. Any such filing shall be served on Plaintiff's Designated Counsel and Plaintiffs' Liaison Counsel, with any response to such filing to be submitted within ten (10) days following the date of service.

E. Requests for Production to Plaintiffs. At any time after a plaintiff serves a PFS on Defendant's Lead Counsel, defendant may propound and serve on that plaintiff five (5) Requests for Production in accord with Fed. R. Civ. P. 34. Plaintiff will respond in accord with Fed. R. Civ. P. 34.

F. Interrogatories to Plaintiffs. At any time after a plaintiff serves a PFS on Defendant's Lead Counsel, defendant may propound and serve on that plaintiff five (5) Interrogatories in accord with Fed. R. Civ. P. 33. Plaintiff will respond in accord with Fed. R. Civ. P. 33.

G. Physical and Mental Examinations of Plaintiffs. Defendant shall be entitled to conduct physical and/or mental examinations of plaintiffs, in accord with Fed. R. Civ. P. 35, any time after the plaintiff serves on defendant a PFS. Such examinations need not be taken before the close of case-specific fact discovery in MDL 1760, but also may be taken after remand during the period provided for expert discovery. All examinations must be completed at a point sufficiently in advance of the close of expert discovery to allow plaintiff to conduct the discovery described in Fed. R. Civ. P. 35(b)(1) prior to the close of any period established for expert discovery.

H. Depositions of Plaintiff. The defendant shall be entitled to take the deposition of each plaintiff.

XI. DISCOVERY FROM THIRD PARTIES.

A. Document Subpoenas to Non-Parties. Upon entry of this Order, any party may serve subpoenas on non-parties for the production of documents without testimony pursuant to Fed. R. Civ. P. 45.

B. Depositions of Non-Parties. Defendant shall be entitled to conduct a total of fifteen (15) depositions of non-parties per plaintiff and each plaintiff shall be entitled to conduct a total of fifteen (15) depositions of non-parties as part of case-specific fact discovery in each case transferred to this Court or otherwise made a part of MDL 1760. For purposes of this Order, treating physicians are considered "fact" witnesses. Absent agreement by the opposing party, the party seeking to notice additional depositions may apply to the Court to conduct further depositions only upon a showing of good cause and the specific identification of the individuals(s) sought to be deposed.

C. *Ex Parte* Communications. The Court finds that *ex parte* communications with plaintiffs' treating physicians will expedite the discovery process and reduce expenses in this litigation. Therefore, counsel for defendant may informally meet with the treating physicians of plaintiffs without providing notice to plaintiffs' counsel and outside the presence of plaintiffs' counsel.

XII. COMPLETION OF FACT DISCOVERY.

Except as agreed to by the parties or where the Court has entered an order providing otherwise, case-specific fact discovery in each specific action shall be completed no later than twelve (12) months after the date upon which all plaintiffs to the specific action provide a PFS complete in all respects to defendant. Absent mutual consent of the parties thereto or further

order of the Court, no case shall be subject to remand to its transferor court prior to the deadline for the completion of fact discovery applicable in that case.

XIII. EXPERT DISCOVERY.

Experts will be disclosed and expert discovery will be conducted on class certification issues pursuant to a Court ordered discovery and briefing schedule. Whether there will be a need for any additional expert opinion and discovery on general issues in this MDL will be determined after the class certification question is resolved. All case-specific expert discovery and related disclosures will be deferred until after the cases are remanded to the transferor courts. Expert depositions taken in this MDL shall be limited to five (5) non-consecutive days of eight hours of deposition testimony for each expert designated.

XIV. REMAND.

Upon the expiration of the deadline for the completion of fact discovery in a specific case, the Court will consider whether issuance of a suggestion of remand to the transferor court is appropriate. In determining whether to issue a suggestion of remand, the Court will consider whether case-specific fact discovery has been fully completed in accordance with this Order. If any plaintiff has not completely complied with the discovery requirements set forth in this or subsequent Orders of this Court, including the completion of a PFS, his or her case shall not be considered for remand until the Court has determined that the discovery obligations of the plaintiff have been completed and defendant has had sufficient time to complete case-specific fact discovery. Remand to the transferor court pursuant to 28 U.S.C. §1407 in no way reflects a waiver of defendant's right to contend that a court other than the transferor court is the

appropriate forum in which to try the case and also in no way reflects any conclusion by this Court that the transferor forum is the appropriate forum for trial in any particular case.

XV. REMAND PROCEDURE.

A. Petition for Suggestion of Remand Order. At any time after a case is ripe for remand, counsel of record for any party to the case may file a Petition for Suggestion of Remand Order ("Petition"). A separate Petition must be filed in each case for which remand is sought. Counsel of record shall not file a Petition unless they can certify in good faith that the case(s) for which remand is sought is have completed all the requirements set forth in this or subsequent orders and the period established elsewhere in this Order has expired.

B. Objections and Responses. A party to a case may file a written objection to a Petition within twenty (20) days of the date of filing. Any party may object to a Petition. The written objection shall identify all reasons why the case is not ripe for remand. Within five (5) days of filing of an opposition, the petitioning party may file a response that shall be limited to five (5) pages.

C. Eligibility for Remand. Any case in which a Petition has been filed will be deemed eligible for remand if (a) no written objection is filed within twenty (20) days of the filing of the Petition, or (b) upon the Court overruling any written objection to the Petition. A party whose case has been deemed not eligible for remand as a result of a successful objection to a Petition may file a subsequent Petition after curing the grounds on which the objection was sustained. The Court will regularly issue Suggestion of Remand Orders, to be forwarded to the JPML, listing all cases that are eligible for remand at that time.

D. Final MDL Pretrial Order. Within seven (7) days of the issuance of a Suggestion of Remand Order by this Court, the parties will submit a joint proposed Final MDL Pretrial Order for the Court's signature. Such order will describe the events that have taken place in MDL 1760 and those items that require further action by the transferor court. A copy of the Final MDL Pretrial Order, along with the case file and materials, will be provided to the transferor court. That order will set forth the parties' positions regarding the schedule for completion of expert discovery after remand, the schedule for the filing of dispositive motions and motions to exclude expert testimony under *Daubert*, and each party's estimate regarding the anticipated length of trial. The Court will enter the Final MDL Pretrial Order upon issuance of a Conditional Remand Order by the JMPL.

XVI. SCHEDULE OF PRETRIAL PROCEEDINGS.

The parties were unable to reach agreement on proposed schedules and are therefore submitting competing proposals. Both proposals are included.

A. Plaintiffs' Proposed Schedule. The following schedule shall govern proceedings in this cause:

1. On or before February 2, 2007, the Plaintiffs shall serve the Defendant with affidavits (by lay or expert witnesses) and expert reports upon which Plaintiffs are relying with respect to class certification (including without limitation an expert report or expert affidavit by each person the Plaintiff may call to testify as an expert witness at the hearing on class certification).

2. On or before March 2, 2007, the Defendant shall serve the Plaintiffs with affidavits (by lay or expert witnesses) and expert reports upon which the Defendant is relying

with respect to class certification (including without limitation an expert report or expert affidavit by each person the Defendant may call to testify as an expert witness at the hearing on class certification).

3. On or before April 20, 2007, Plaintiffs shall give notice in writing, including a definition of the proposed class, of their desire to be granted class certification.

4. On or before May 21, 2007, the Defendant shall file its memorandum in opposition to class certification.

5. On or before June 15, 2007, Plaintiffs shall file their memorandum in support of class certification under Fed. Rule Civ. Proc. 23(b)(2) and/or 23(b)(3).

6. On or before June 30, 2007, Defendant shall file its reply memorandum in further opposition to class certification.

7. If the Court requests the parties to submit proposed findings of fact and conclusions law on class certification, these shall be due as the court may require.

8. On or before April 3, 2007, the parties shall file motions to name additional parties or otherwise amend their pleadings.

9. On or before April 27, 2007, the Plaintiffs shall provide the Defendant with Plaintiffs' Rule 26(a)(2) disclosures and serve Defendant with reports or affidavits of testifying experts on issues common to all of plaintiffs' cases and all issues in the case(s) set for trial in the Middle District of Tennessee pursuant to this Order.

10. On or before May 28, 2007, the Defendant shall provide the Plaintiffs with its Rule 26(a)(2) disclosures and serve the Plaintiff with reports of affidavits of testifying experts on issues common to all of Plaintiffs' cases and all issues in the case(s) set for trial in the Middle

District of Tennessee pursuant to this Order.

11. On or before June 1, 2007, all fact-based discovery in cases in which the stay on discovery has been lifted shall be completed.

12. On or before June 11, 2007, the Plaintiffs may supplement the Plaintiffs' expert reports or affidavits. Except for good cause shown, further supplementation shall be permitted thereafter. Opportunity for supplementation as it relates to expert reports or affidavits is not intended to excuse the Plaintiffs from fully complying with the initial expert disclosure obligation, but instead is intended to provide for disclosure of expert work that is truly in the nature of rebuttal of the Defendant's expert(s).

13. All discovery motions, except as may subsequently arise with respect to experts, in case(s) set for trial in the Middle District of Tennessee pursuant to this Order shall be filed on or before June 18, 2007.

14. On or before June 22, 2007, the Defendant may supplement it expert reports or expert affidavits. Except for good cause shown, no further supplementation shall be permitted. The opportunity for supplementation, as it relates to expert reports or affidavits, is not intended to excuse the Defendants from fully complying with the initial expert disclosure obligation, but instead is intended to provide for disclosure of expert work that is truly in the nature of sur-rebuttal of the Plaintiff's experts(s).

15. On or before August 31, 2007, discovery of experts common to all cases and all experts in case(s) set for trial in the Middle District of Tennessee pursuant to this Order shall be completed and any discovery motions pertaining to experts shall be filed.

16. On or before September 30, 2007, in case(s) set for trial in the Middle District of

Tennessee pursuant to this Order the parties shall file all motions for summary judgment, other potentially dispositive motions (including FRCP 12 motions), motions relating to the admissibility of expert testimony, and motions for Daubert hearings.

17. On or before November 5, 2007, in case(s) set for trial in the Middle District of Tennessee pursuant to this Order, the parties shall file motions in limine and any motions objecting to expert testimony. Any response to such motion shall be filed by November 12, 2007.

18. Counsel shall submit a joint proposed pre-trial order to the Court by November 12, 2007, in case(s) set for trial in the Middle District of Tennessee pursuant to this Order. The pre-trial order shall contain: (1) a recitation that the pleadings are amended to conform to the pre-trial order and that the pre-trial order supplants the pleadings; (2) a statement of the basis for jurisdiction of this Court; (3) a short summary of Plaintiffs' theory (no more than one page); (4) a short summary of Defendant's theory (no more than one page); (5) a statement of the issues, including designation of which issues are for the jury and which are for the Court; (6) a statement of the relief sought; (7) a summary of any anticipated evidentiary disputes; and (8) and estimate of the anticipated length of trial.

19. Also, by November 12, 2007, in case(s) set for trial in the Middle District of Tennessee pursuant to this Order, the parties shall submit to the Court:

(a) A joint proposed jury instruction and verdict forms as follows:

Counsel shall exchange proposed jury instructions on substantive law of this specific case and proposed verdict forms and confer to reach agreement. Thereafter, counsel shall jointly prepare and file a set of agreed, proposed, case-specific jury

instructions and verdict forms. Each proposed jury instruction shall begin with a new page and shall include the citations to supporting authorities. Counsel shall separately file any disputed jury instructions or verdict forms.

Certain standard non-case specific jury instructions generally used by the Court are available on the Court's website: http//www.tnmd.uscourts.gov/campbell.html. Counsel with internet access shall file any objections to these standard jury instructions.

If possible the parties shall submit a word perfect compatible computer disc of the agreed proposed jury instructions and verdict forms with hard copy;

(b) witness lists, except for witnesses solely for impeachment in accordance with FRCP 26(a)(3);

(c) exhibit lists, except for documents solely for impeachment in accordance with FRCP 26(a)(3); and

(d) any stipulations.

20. Counsel for the parties in case(s) set for trial in the Middle District of Tennessee pursuant to this Order shall appear for a pre-trial conference in this Court on November 19, 2007 at 9:00 a.m. All lawyers who will participate in the trial must attend the pre-trial conference.

21. One or more cases subsequently to be determined shall be set for trial on November 27, 2007. It is anticipated that the trial of this cause will take three (3) weeks.

B. Defendant's Proposed Schedule for the Putative Class Actions Originally Filed in the Middle District of Tennessee. Plaintiffs' proposal is similar to the schedule in place in *Wood v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0716 (M.D. Tenn.) prior to the creation of the MDL. Presently, both plaintiffs and the Court have expressed skepticism about

the viability of the putative personal injury classes pled in the three original Middle District of Tennessee cases. Plaintiffs have indicated that they may replead and request a dental monitoring class. However, in their proposal, plaintiffs do not provide any information about the type or scope of the class they plan to assert. Defendant and the Court have no information regarding who or how many purported representatives that class may have and therefore defendant contends that establishing a class certification briefing and discovery schedule would be both impractical and a violation of its various due process and other rights. Defendant initially proposes that if/when plaintiffs finalize their request for certification of a dental monitoring or other class and file a sufficient class action complaint, the parties will meet and confer regarding an appropriate schedule for class discovery and briefing. However, should this Court decide to establish a class certification discovery and briefing schedule now, defendant's proposed schedule for both the three original Middle District of Tennessee cases and all other MDL cases follows.

This schedule maintains the time periods originally contained in Judge Campbell's pre-MDL case management order EXCEPT it adds 90 days for the submission and completion of the PFS and six months to compensate for discovery time under the initial schedule lost to defendant beginning at the time the request for an MDL was filed, from which point plaintiffs declined to provide defendant with valid authorizations allowing collection of medical records for some plaintiffs or deposition dates for other plaintiffs.

C. Discovery of the Three Putative Class Actions Originally Filed in the Middle District of Tennessee. Discovery in Case Nos. 3:05-CV-00716; 3:05-CV-00718; and 3:05-CV-00719 will be conducted in two phases. The first phase will address class certification and will

be completed on December 7, 2007. The second phase will address the merits of the actions. Discovery of all other cases transferred to this Court for inclusion in MDL 1760 shall be conducted as set forth below.

D. Class Certification Phase (Case Nos. 3:05-CV-00716; 3:05-CV-00718; and 3:05-CV-00719).

1. In the initial phase, discovery shall be addressed to matters bearing on class certification. The parties are directed to work together in a good faith effort to resolve any disputes that may arise between them on the issue of whether discovery is class or merits related before seeking Court intervention.

2. For good cause shown, the sixty (60) day requirement of Local Rule 23.01(b) is waived. Plaintiffs shall file their Motion for and Memorandum in Support of Class Certification in accordance with the schedule set forth below.

3. Discovery shall commence with the transmission by Plaintiffs' Liaison Counsel or his designee on or before August 14, 2006 of a blank PFS to each plaintiff whose claims were originally included in the three actions filed in this District (Case Nos. 3:05-CV-00716; 3:05-CV-00718; and 3:05-CV-00719). Plaintiffs' Liaison Counsel shall certify transmission of the PFS to each plaintiff to Defendant's Lead Counsel. These plaintiffs shall constitute "Wave One Plaintiffs" for purposes of discovery of plaintiffs.

4. Sixty days after the date of this Order, all MDL plaintiffs may commence discovery of defendant as set forth elsewhere in this Order. Discovery of defendant will not be in waves and must be coordinated among all plaintiffs as set forth elsewhere in this Order.

5. On or before September 28, 2006 (45 days after service), each plaintiff shall serve a PFS, complete in all respects (as defined elsewhere in this Order), upon Defendant's Lead Counsel.

6. On October 2, 2006, defendant may commence depositions of the Wave One Plaintiffs, including but not limited to depositions of plaintiffs, treating and consulting physicians, and family and friends of plaintiffs.

7. On or before August 3, 2007, plaintiffs shall serve defendant with all affidavits (by lay or expert witnesses) and expert reports upon which plaintiffs are relying with respect to class certification (including without limitation an expert report or expert affidavit by each person plaintiffs may call to testify as an expert witness at the hearing on class certification).

8. All fact discovery related to class certification shall be completed by August 31, 2007.

9. On or before September 7, 2007, defendant shall serve plaintiffs with all affidavits (by lay or expert witnesses) and expert reports upon which defendant is relying with respect to class certification (including without limitation an expert report or expert affidavit by each person defendant may call to testify as an expert witness at the hearing on class certification).

10. All discovery motions regarding class certification fact discovery shall be filed by October 1, 2007.

11. All expert discovery related to class certification shall be completed no later than October 19, 2007.

12. On or before November 15, 2007, plaintiffs shall file their motion for and memorandum in support of class certification.

13. On or before December 7, 2007, defendant shall file its memorandum in opposition to plaintiffs' motion for class certification.

14. On _____, at _____, a hearing before the Court on plaintiffs' motion for class certification shall occur.

15. If the Court requests that the parties submit proposed findings of fact and/or conclusions of law on class certification, these shall be due as the Court may require.

E. Merits Phase (Case Nos. 3:05-CV-00716; 3:05-CV-00718; and 3:05-CV-00719). As of the date of this Order, no plaintiff is a resident of this District and defendant contends that there is no case that is a viable candidate for trial in this District. Further, plaintiffs also have not clarified whether the three actions originally filed in this district as nationwide personal injury class actions will be abandoned or otherwise converted into individual claims, or whether a different type of class, such as a dental monitoring class, will be sought. Therefore, defendant believes that a merits schedule leading to trial of any individual case should not be set. However, in response to this Court's request for a proposed trial schedule, defendant proposes the following without waiving its right to challenge whether this District is a suitable trial venue at the appropriate time.

1. On December 7, 2007, the parties may commence additional discovery related to the merits of the claims and defenses of the cases.

2. On or before January 4, 2008, the parties shall file any motions to name additional parties or to amend their pleadings. The Court shall sever any joint actions into single

plaintiff actions, except that loss of consortium claims will remain in the same action as the related injury claims.

3. On or before January 7, 2008, the parties shall brief the appropriate venue of the severed actions for trial.

4. Should any individual action(s) be tried in this Court, the individual action(s) shall proceed on separate tracks so as to stagger trial and other key dates. Separate scheduling orders will be entered in each case after consideration of this Court's docket. Parties can expect the first case to proceed on the following schedule, with deadlines in the remaining cases to be staggered by at least three to six weeks.

5. On or before February 8, 2008, plaintiff shall provide defendant with plaintiff's Fed. R. Civ. P. 26(a)(2) disclosures and serve defendant with reports or affidavits of testifying experts.

6. On or before March 7, 2008, defendant shall provide plaintiff with its Fed. R. Civ. P. 26(a)(2) disclosures and serve plaintiff with reports or affidavits of its testifying experts.

7. On or by March 14, 2008, all fact discovery shall be completed.

8. On or before March 24, 2008, plaintiff may supplement plaintiff's expert reports or expert affidavits. No further supplementation shall be permitted. The opportunity for supplementation, as it relates to expert reports or affidavits, is not intended to excuse plaintiff from fully complying with initial expert disclosure obligations, but instead is intended to provide for disclosure of expert work that is truly in the nature of rebuttal to defendant's expert(s).

9. All discovery motions regarding merits discovery shall be filed by April 4, 2008.

10. On or before April 11, 2008, defendant may supplement its expert reports or expert affidavits. No further supplementation shall be permitted. The opportunity for supplementation, as it relates to expert reports or affidavits, is not intended to excuse defendant from fully complying with its initial expert disclosure obligations, but instead is intended to provide for disclosure of expert work that is truly in the nature of sur-rebuttal to plaintiff's expert(s).

11. On or by April 25, 2008, all expert discovery shall be completed.

12. On or before May 16, 2008, the parties shall file all motions for summary judgment, other potentially dispositive motions (including Fed. R. Civ. P. 12 motions), motions related to the admissibility of expert testimony, and motions for a *Daubert* hearing.

13. By August 18, 2008, the parties shall file any motions in limine and any motions objecting to expert testimony. Any responses to such motions shall be filed by August 25, 2008.

14. Counsel shall submit a Joint Proposed Pretrial Order to the Court by August 25, 2008. The Pretrial Order shall contain: (1) a recitation that the pleadings are amended to conform to the Pretrial Order and that the Pretrial Order supplants the pleadings; (2) a statement of the basis for jurisdiction in this Court; (3) a short summary of plaintiff's theory (no more than one page); (4) a short summary of defendant's theory (no more than one page); (5) a statement of the issues, including a designation of which issues are for the jury and which are for

the Court; (6) a succinct statement of the relief sought; (7) a summary of any anticipated evidentiary disputes; and (8) an estimate of the anticipated length of the trial.

15. Also by August 25, 2008, the parties shall submit to the Court:

a. Joint proposed jury instructions and verdict forms as follows:

i. Counsel shall exchange proposed jury instructions on the substantive law of this specific case and proposed verdict forms and confer to reach agreement. Thereafter, counsel shall jointly prepare and file a set of agreed, proposed, case specific, jury instructions and verdict forms. Each proposed jury instruction shall begin on a new page and shall include citations to supporting authorities. Counsel shall separately file any disputed jury instructions or verdict forms.

ii. Certain standard, non-case specific jury instructions generally used by the Court are available on the Court's website: http//www.tnmd.uscourts.gov/Campbell.html. Counsel with internet access shall file any objections to these standard jury instructions.

If possible, the parties shall submit a Word Perfect compatible computer disk of the agreed proposed jury instructions and verdict forms with the hard copy;

b. Witness lists, except for witnesses solely for impeachment in accordance with Fed. R. Civ. P. 26(a)(3);

c. Exhibit lists, except for documents solely for impeachment in accordance with Fed. R. Civ. P. 26(a)(3); and

d. Any stipulations.

16. Counsel for the parties shall appear for a Pretrial Conference in this Court on September 8, 2008 at _____. All lawyers who will participate in the trial must attend the pretrial conference.

17. Trial Date: September 15, 2008 at _____.

F. Defendant's Proposed Schedule for the Remaining MDL Cases.

1. Discovery of those cases transferred to MDL 1760 other than Case Nos. 3:05-CV-00716; 3:05-CV-00718; and 3:05-CV-00719 shall commence with the transmission by Plaintiffs' Liaison Counsel or his designee on December 27, 2006 of a blank PFS (as described elsewhere in this Order) to each plaintiff whose claims were originally filed in or before January 2006 and who was not part of the Wave One Plaintiffs. Plaintiffs' Liaison Counsel shall certify transmission of the PFS to each plaintiff to Defendant's Lead Counsel. These plaintiffs shall constitute "Wave Two Plaintiffs" for purposes of discovery of plaintiffs.

2. On or before February 12, 2007, each Wave Two Plaintiff shall serve a PFS, complete in all respects (as defined elsewhere in this Order), upon Defendant's Lead Counsel.

3. One hundred and fifty days (150) after submission by each plaintiff of a PFS that is compete in all respects, defendant may commence depositions regarding Wave Two Plaintiffs, including but not limited to depositions of Wave Two Plaintiffs, treating and consulting physicians, and family and friends of Wave Two Plaintiffs.

4. On or before May 14, 2007, Plaintiffs' Liaison Counsel shall transmit a blank PFS to each plaintiff whose case was originally filed in February 2006. Plaintiffs' Liaison

Counsel shall certify transmission of the PFS to each plaintiff to Defendant's Lead Counsel. These plaintiffs shall constitute "Wave Three Plaintiffs" for purposes of discovery of plaintiffs.

5. On or before June 28, 2007, each Wave Three Plaintiff shall serve a PFS, complete in all respects (as defined elsewhere in this Order), upon Defendant's Lead Counsel.

6. One hundred and fifty days (150) after submission by each plaintiff of a PFS that is compete in all respects, defendant may commence depositions regarding Wave Three Plaintiffs, including but not limited to depositions of Wave Three Plaintiffs, their treating and consulting physicians, and family and friends of Wave Three Plaintiffs.

7. Discovery of plaintiffs in cases filed in months following February 2006 shall commence in later waves. The commencement of discovery for each wave shall occur 90 days after the due date for PFSs complete in all respects from the prior wave of plaintiffs, *e.g.*, discovery of "Wave Four Plaintiffs" shall commence with transmission of a PFS on September 26, 2007 to plaintiffs whose cases were originally filed in March 2006.

8. As provided for elsewhere in this Order, depositions of the remaining waves of plaintiffs, their treating and consulting physicians, and their family and friends, may commence 150 days after each plaintiff has completed the PFS in all respects.

9. Case-specific fact discovery in each specific action shall be completed no later than twelve (12) months after the date upon which each plaintiff in the specific action provides a PFS complete in all respects to defendant.

10. After the completion of case specific fact discovery, counsel of record for any party to a case transferred to MDL 1760 may file a Petition for Suggestion of Remand Order as described above.

It is so **ORDERED** this _____ day of _____, 2006.

_____
JOE B. BROWN
United States Magistrate Judge

Exhibit A

VIA U.S. MAIL

[Recipient Name and Address]

Re: Medical Records for _____
_____ *v. Novartis Pharms. Corp.*, No. _____ (M.D. Tenn.)
Plaintiff: _____; SSN _____
DOB: _____

Dear Dr:_____:

You provided medical treatment to [Plaintiff's name]. [Plaintiff's name] is currently a plaintiff in litigation against Novartis Pharmaceuticals Corporation pending in the United States District Court for the Middle District of Tennessee captioned [specific case caption]. Records regarding your care and treatment of [Plaintiff's name] may be sought in that litigation.

You are hereby notified that, on _____, 20___, the Court entered an Order precluding the "altering, destroying, permitting the destruction of, or in any other fashion changing any document or tangible item in the actual or constructive care, custody, or control of such person that is reasonably within the scope of discovery in this case, wherever such document or tangible item is physically located." Order of ___, 2006 at __. The medical records related to [Plaintiff's name] in your possession reasonably fall within the scope of discovery in this case. In accordance with the Court's Order, you should take any and all appropriate steps to ensure that those records, including x-ray films and any other images, are not altered, destroyed, or otherwise changed until such time as the above-referenced litigation is completed.

Thank you for your attention to this matter.

Plaintiff's Counsel

cc: Joe G. Hollingsworth, Esq.
Katharine R. Latimer, Esq.